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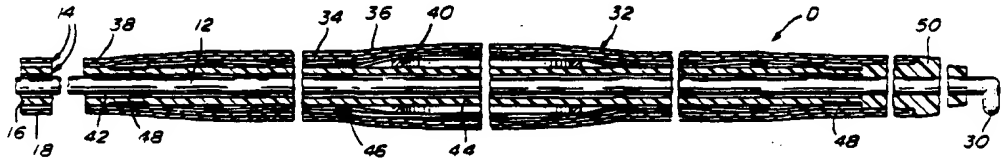

(57) Abstract

An expandable prosthesis to be positioned in a parenchymal tract joining in the liver the hepatic and portal veins comprises a first substantially rigid tubular member and a second substantially flexible tubular member. The first and second tubular members each have a first collapsed diameter and at least a second expanded diameter and are adapted to at least partly overlap one another when installed in the body passageway. Basically, the rigid member provides rigidity to the prosthesis while assisting in maintaining in position the prosthesis in the passageway, whereas the flexible member assists the prosthesis in substantially following the orientation of the body passageway. In a shunting device, a catheter is provided for detachably carrying the prosthesis and for positioning the same in the body. An expandable balloon is used to expand the rigid tubular member, whereas the flexible tubular member which has intrinsic self-expanding forces expands when a sheath is removed. Therefore, the rigid and flexible tubular members are expanded to the respective expanded diameters thereof.

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ENDOVASCULAR HEPATIC PROSTHESES

TECHNICAL FIELD

The present invention relates to endovascular hepatic prostheses and, more particularly, to improved intrahepatic portal-systemic shunts.

BACKGROUND ART

Hepatic insufficiency is a known reversible state which leads to death in a relatively short time. In such case, a hepatic transplant is considered as the best treatment. Sadly, patients often have to wait for a substantially long period of time, e.g. more than one year, before obtaining a graft. During this period, numerous complications of the hepatic insufficiency may appear in an unpredictable manner. These complications which are often linked to portal hypertension (the less than efficient functioning of the liver results in the elevation of the blood pressure at the level of the portal vein which carries to the liver a circulation which corresponds approximately to 30% of the cardiac flow) include the rupture of esophageal varices (the dilatation and then rupture of the fragile veins of the esophagus) and the medico-resistant ascites with kidney insufficiency (when there is too much pressure in the liver, it leaks; then water accumulates in the abdomen, whereby an ionic disequilibrium is produced at the level of the kidneys and it is then necessary to administer diuretics; these drugs acting only for a short period of time, it is thus necessary to effect some

punctures). These two complications are responsible for two-thirds of the death of patients suffering from hepatic insufficiency. Finally, during the terminal hepatic insufficiency, numerous metabolic hepatic functions fail and compromise the immediate survival of the patients. These complications can plunge the patients awaiting a graft in such a state that the transplant becomes impossible to realize with an acceptable success rate. While awaiting a liver graft, the patients thus live in a state of semi-emergency.

For digestive hemorrhage resulting from esophageal varices, surgical treatment (portacaval shunt, i.e. blood is diverted from the portal vein to the vena cava) is not suggested in view of a high mortality rate (major surgery) and of the risk of endangering technically a subsequent hepatic transplant. The treatment by drugs (beta-blockers) is not efficient in all cases and the patients are exposed to hemorrhagic recurrences. The endoscopic sclerotherapy of varices is presently the most used method of treatment (a sclerosing agent is injected in the esophageal veins). Sadly, a plurality of injections at intervals of a couple of weeks are necessary to obliterate the esophageal varices, and the hemorrhagic recurrence (the mucosa is sclerosed, an ulcer is formed, which then bleeds) between the sessions is frequent and can precipitate in a rapidly developing terminal hepatic insufficiency for patients awaiting a hepatic graft.

With respect to the ascites, when it becomes impossible to treat them by means of diuretics (medico-resisting ascites), the only valid alternative is the treatment by repeated punctures

of the abdominal liquid, most often weekly or every two weeks, thereby resulting in a degraded quality of life and high risks of infections. Surgical treatments are also in this case efficient, but the mortality rate is prohibitive.

Expandable intraluminal stents were initially developed for preventing reocclusion of delayed restenosis after percutaneous transluminal balloon angioplasty of occluded arteries. Intraluminal metal stents were then used in the biliary system in an animal model. Expandable biliary stents are introduced through a small transhepatic tract and, once in place, are expanded to a larger diameter for maintaining antegrade bile flow for a long period of time.

Intrahepatic portal-systemic shunt is characterized by the creation of a fistulous tract between branches of the hepatic and intrahepatic portal veins through the intervening hepatic parenchyma. In their crudest form, intrahepatic portal-systemic shunts are simply parenchymal tracts connecting the two vessels. Transjugular intrahepatic portal-systemic stent-shunts are more specific in using expandable metal stents which have been placed between branches of the portal and systemic venous systems. The acronym TIPS is used for the transjugular intrahepatic portal-systemic shunts.

The procedure is almost always formed through the jugular vein thereby explaining the use of the term "transjugular". On the other hand, the procedure can also be performed through the femoral veins. The exact anatomic sight of the skin puncture

is irrelevant. In any event, the term TIPS will be herein used to cover all intrahepatic portal-systemic shunt procedures.

Basically, there are two types of expandable metal stents: balloon expandable stents which are expanded by inflation of an angioplasty balloon, and self-expandable stents which have an intrinsic expanding force.

A well-known balloon expandable stent is the Palmaz stent which is an expandable metal stent for intraarterial use that was employed to keep the hepatic parenchymal tract patent. The Palmaz stent is a seamless tube of electropolished medical grade stainless steel, with staggered parallel slots defined through its wall. In the collapsed state, the Palmaz stent has a diameter of 3.1 mm and the length of 30 mm. For positioning, the Palmaz stent has to be crimped on a high pressure, Gruentzig-type balloon. By expanding this angioplasty balloon, the stent is dilated to a predetermined diameter (i.e. 8 to 12 mm). Full expansion reduces the length of the stent to 25 mm. With the expansion of the Palmaz stent, the slots defined in the wall thereof assume a diamond shape and the open area within the metal mesh increases to a maximum of 88%. The Palmaz stent is rigid in the longitudinal axis thereof and has a very high resistance to circumferential radial pressure. The stent is fairly radiopaque. The balloon mounted Palmaz stent is inserted through a 10 F, 40 cm long introducer sheath. A metallic introducing cannula is required to pass the Palmaz stent through the sheath valve.

The 10 F sheath is withdrawn proximal to the balloon and a test injection is performed to check the position of the stent which can be corrected, if required. The Palmaz stent is then deployed by injecting a mixture of saline and dye into the angioplasty balloon. As the ends of the Palmaz stent expand first, movement of the stent after partial expansion thereof is dangerous and has to be avoided. After complete deflation of the balloon, the sheath can again be advanced and the angioplasty balloon catheter can be withdrawn. Since the Palmaz stent is short, multiple stents may have to be placed in an overlapping end-to-end fashion. Gradually, the shunt while remaining patent becomes covered by a layer of endothelial cells.

The second type of expandable metal stent, that is the self-expandable stent having an intrinsic expanding force is made of biomedical superalloy monofilament wire (cold-formed cobalt-chromium-nickel-molybdenum-iron alloy) braided in a tubular mesh configuration, the stent being flexible, compliant and self-expanding. The wire mesh consists of twenty-four braided wires with unfixed crossing points. The compressed stent premounted on a 7 F catheter has a length of 42 or 68 mm and a diameter of 2 mm. After release, the stent expands to a diameter of 8 or 10 mm and its length reduces by approximately 32%. An example of such a self-expandable stent having an intrinsic expanding force is the Wallstent™ which has longitudinal and radial elasticity and which, after deployment and fixation of the stent at the proximal and distal ends thereof, is moderately resistant to circumferential stress. It is noted that the stent has low radiopacity.

The Wallstent™ is premounted on a 7 F catheter and then covered by a thin invaginated rolling polyurethane membrane which serves to keep the stent compressed during the insertion thereof. Therefore, the Wallstent™ can be inserted through a regular 7 F catheter introducer sheath. To deploy the stent, the two sheaths of the invaginated rolling membrane are separated hydraulically and the membrane is retracted.

The Wallstent™ will pass through a 7 F catheter introducer sheath and the stent will be inserted in a single step procedure. The Wallstent™ catheter has been prepared by filling the hydraulic membrane with contrast material. The 7 F sheath is withdrawn to avoid compressing the hydraulic membrane. The Wallstent™ catheter is properly positioned across the intra-parenchymal tract by way of the radiopaque markers provided thereon (one at both ends of the stent and a middle marker which indicates the shortening). Under a predetermined pressure, the hydraulic membrane is withdrawn thereby allowing the deployment of the Wallstent™. Corrections to the stent position are possible as long as the membrane holds the stent on the catheter. It is important to maintain the proper pressure (e.g. 3.0 atm) during device preparation and stent deployment as under-pressurization may cause the rolling membrane to be perforated by the stent, whereas over-pressurization may cause the rolling membrane to rupture. A damaged rolling membrane may impede the proper placement of the stent in the liver.

Other stents than the above-described Wallstent™ and Palmaz stent have also been used, such as the Strecker stent, the Gianturco-Rösch biliary Z-Stent, and the Cragg stent.

The insertion and deployment of an intrahepatic portal-systemic stent is one of the most complex procedures in interventional medicine, and two stents are now widely used, that is the above Palmaz balloon expandable stent and the Wallstent™, the former being a relatively rigid stent that is usually expanded to 12 mm in diameter but can be expanded to 16 mm, while the former is a self-expanding stent that is much more flexible than the Palmaz stent. The Wallstent™ retains its circular shape even when flexed at relatively sharp angles; furthermore, because of its flexibility, the Wallstent™ is easier to insert.

More particularly, the surgical procedure includes the following steps with respect to a Wallstent™ which is passed through the right jugular vein. An angiography catheter is guided into a large hepatic vein and then replaced by a Colapinto transjugular needle which is directed towards the hepatic parenchyma towards the hilum of the liver. The needle is slowly withdrawn under suction and when blood is aspirated, the vessel is identified by contrast injection. The needle is replaced by a balloon catheter within the Colapinto catheter after the portal vein is entered. The balloon catheter is positioned across the parenchymal tract and inflated with contrast medium to a diameter of 10 mm. The balloon and Colapinto catheters are then removed and, for instance, a 7 F delivery catheter is passed, a Wallstent™ covered

by a retractable plastic sheath or membrane being mounted on this delivery catheter. Depending on the length of the tract, an appropriate stent is deployed by pulling back the membrane which detaches the stent from the catheter in view of the intrinsic expanding force of the stent. The stent thus deploys to extend completely through the parenchymal tract, extending about 5 mm into both the hepatic and portal veins. It is noted that if the stent is too short, a second overlapping stent can be distended within the original one thereby increasing the length of the endoprostheses (as for the Palmaz stent).

The Palmaz stent is more difficult to insert because of its rigidity and it is thus required to insert the Palmaz stent into larger, more centrally located veins. On the other hand, once it is distended, its larger diameter alloys for a single shunt to decompress the portal system completely, whereas complete decompression with the Wallstent™ may require the deployment of two distinct hepatic portal shunts, e.g. having 8 and 10 mm diameters.

If a pseudointimal hyperplasia develops and thereby causes stenosis of the shunt, a new stent can be positioned within the original one and expanded to restore the lumen virtually to its original diameter.

After installation of an intrahepatic portal-systemic shunt, or TIPS, most peripheral portal veins show retrograde blood flow, thus indicating that blood is being shunted.

Accordingly, intrahepatic portal-systemic shunts or stents are especially well suited to patients awaiting liver transplantation and it is a much less invasive procedure than surgical portal-systemic anastomosis which cannot be tolerated in most such patients. Furthermore, the existence of an intrahepatic stent that is removed during hepatectomy does not increase the technical difficulty of performing a liver transplant, as surgical portal-systemic shunts often do. In addition, intrahepatic portal-systemic shunts appear, by reducing portal hypertension and mobilizing ascites, to improve nutrition and thus to improve hepatic function enough to eliminate entirely the need for a new liver in some patients.

Intrahepatic portal-systemic shunts or stents however, can produce complications, principally such as hepatic encephalopathy (i.e. HE) and stent stenosis which leads in some cases to occlusion of the stent.

It has been observed that surfaces of the shunts after one week of stenting were slightly irregular, and small thrombi adhered to the stent wires. Endothelial cells were present in patches but the endothelial lining was incomplete. Three weeks after stenting, the surface was smooth and free of thrombi and a complete organized layer of endothelial cells lined the luminal surface of the shunt.

As the development of loose connective tissue beneath the endothelial layer occurs in some cases, stenosis or, ultimately, occlusion of the shunt is correctable by the deployment of a new

stent inside the old one, the new stent having a slightly smaller diameter than the original one.

On the other hand, a positive aspect of intrahepatic portal-systemic shunts or stents lies in its high rate of successful implantation and its low incidence of complications. Studies of the body's response to these foreign bodies or prostheses inserted into the center of the liver show that these stainless steel stents are accepted by the liver and are promptly covered by endothelium. Indeed, the wires are quickly coated by endothelial and subintimal tissue which is then remodeled to similate natural blood vessels. Obviously, an overly exuberant intimal generation can result in pseudointimal hyperplasia which can cause stenosis or obstruction of the shunt. Most failures of these stents, manifested by recurrent variceal bleeding, are the result of such stenoses. In any event, some stents have remained functional for more than four years and it appears that with TIPS, as with liver transplants, adverse effects tend to occur early after implantation.

Again, intrahepatic portal-systemic shunts or stents reduce portal venous pressure and blood flow through esophagogastric varices and, by these alterations in the pathophysiology of portal hypertension, reduce the risks of bleeding from varices. For many years, surgical portacaval anastomoses have been constructed to accomplish these goals. Although such shunts have been shown to decrease the incidence of bleeding from varices, the surgical risks of such major procedures are considerable. On the other hand, intrahepatic portal-systemic shunting is a much less invasive

procedure that is faster, safer and less expensive. Again, it is much easier and safer to perform liver transplantation in patients with intrahepatic portal-systemic shunts than in patients having conventional surgical portal-systemic shunts. It has been shown that liver transplantation in patients having such surgical portal-systemic shunts results in a surgery of longer duration, greater difficulty, higher transfusion requirements and perhaps, decreased survival rate.

The rigid Palmaz stent has the advantages that it basically cannot migrate in the liver and that it cannot be crushed or flattened by circumferential pressure. On the other hand, the Palmaz stent lacks the flexibility for assuming or negotiating the necessary curved configuration dictated by an intrahepatic portal-systemic shunt. This curved configuration could be negotiated by a series of rigid Palmaz stents connected successfully one to the other in an end-to-end manner, although such a procedure is relatively lengthy and complicated.

On the other hand, the Wallstent™ flexible stent has the advantage that its intrinsic flexibility allows the stent to easily follow the curved transhepatic tract. However, the flexibility of the Wallstent™ results in that it can be easily flattened or crushed by circumferential pressure and that it can migrate.

DISCLOSURE OF INVENTION

It is therefore an aim of the present invention to provide improved intrahepatic portal-

systemic stents for palliating to certain complications resulting from hepatic insufficiency, such as portal hypertension, while patients await a liver graft. New endovascular prostheses are proposed for preventing ruptures of esophageal varices and for controlling medico-resistant ascites.

It is also an aim of the present invention to provide an intrahepatic portal-systemic stent which comprises at least one flexible section and one substantially rigid section.

It is a further aim of the present invention to provide a method for shunting hepatic blood circulation between the hepatic and portal veins.

Therefore, in accordance with the present invention, there is provided an expandable prosthesis for a body passageway comprising first and second substantially tubular members, one of the first and second tubular members being substantially rigid with another one of the first and second tubular members being substantially flexible, the first and second tubular members each having a first collapsed diameter and at least a second expanded diameter, the first and second tubular members being adapted to at least partly overlap one another when installed in the body passageway, whereby the rigid member provides rigidity to the prosthesis while assisting in maintaining in position the prosthesis in the passageway, whereas the flexible member assists the prosthesis in substantially following the orientation of the body passageway.

More particularly, the first and second tubular members are distinct and each define openworks, at least when expanded.

Also, the rigid member is adapted to be expanded by outwardly directed radial forces while the flexible member is provided with intrinsic self-expanding forces, the flexible member being longer than the rigid member, whereby when the prosthesis is installed end portions of the flexible member extend outwardly past ends of the rigid member.

In a particular embodiment, the rigid member is adapted to be disposed within the flexible member. Alternatively, the flexible member is adapted to be disposed within the rigid member.

If the rigid member is adapted to be disposed in the flexible member, the expanded diameter of the flexible member is smaller than the expanded diameter of the rigid member, whereby the deployment of the rigid member to the expanded diameter thereof within the flexible member causes at least a central portion thereof located between the end portions thereof to overextend thereby substantially securing the rigid and flexible member one to the other when installed in the body passageway.

If the flexible member is adapted to be disposed within the rigid member, the rigid member is expanded to an expanded diameter thereof smaller than the expanded diameter of the flexible member thereby restricting the expansion of the flexible member at least at a central portion thereof located between the end portions thereof, whereby end

portions of the flexible member expand to a larger diameter than the central portion for substantially securing the rigid and flexible member one to the other when installed in the body passageway.

Generally, the rigid member is adapted to be expanded by outwardly directed radial forces while the flexible member is provided with intrinsic self-expanding forces, the flexible and rigid members being adapted to be disposed, when installed in the body passageway, in an end-to-end and slightly overlapping relationship.

More specifically, the flexible member comprises a pair of distinct and similar sections with the rigid member being adapted to be disposed between the pair of sections when the prosthesis is installed in the passageway.

Even more specifically, the rigid member is adapted to be disposed partly within the flexible member, the expanded diameter of the sections of the flexible member being smaller than the expanded diameter of the rigid member, whereby the deployment of the rigid member to the expanded diameter thereof while ends of the rigid member are positioned within the sections of the flexible member causes ends of the sections overlapping the rigid member ends to overextend thereby substantially securing the rigid and flexible member one to the other when installed in the body passageway.

Also in accordance with the present invention, there is provided a shunting device for a body comprising an expandable prosthesis comprising first and second substantially tubular members, one

of the first and second tubular members being substantially rigid with another one of the first and second tubular members being substantially flexible, the first and second tubular members each having a first collapsed diameter and at least a second expanded diameter, catheter means for detachably carrying the prosthesis and for positioning the prosthesis in the body, expansion means for causing the first and second members to extend to the respective expanded diameters thereof, the first and second tubular members being adapted to at least partly overlap one another when installed in the body passageway, whereby the rigid member provides rigidity to the prosthesis while assisting in maintaining in position the prosthesis in the passageway, whereas the flexible member assists the prosthesis in substantially following the orientation of the body passageway.

More particularly, the first and second tubular members are distinct and each define openworks, at least when expanded, the rigid member being adapted to be expanded by outwardly directed radial forces while the flexible member is provided with intrinsic self-expanding forces. The flexible member can be longer than the rigid member, whereby when the prosthesis is installed end portions of the flexible member extend outwardly past ends of the rigid member.

BRIEF DESCRIPTION OF THE DRAWINGS

Having thus generally described the nature of the invention, reference will now be made to the accompanying drawings, showing by way of

illustration a preferred embodiment thereof, and in which:

Figure 1 is a schematic view of an improved shunting device including an intrahepatic portal-systemic stent in accordance with the present invention;

Figure 2 is an enlarged cross-sectional view taken along lines 2-2 of Figure 1 and showing in detail the intrahepatic portal-systemic stent of the present invention;

Figures 3 to 8 schematically illustrate, in order, method steps for producing an intrehepatic shunt using the shunting device of Figure 1 and specifically the intrahepatic portal-systemic stent of Figure 2; and

Figure 9 is a schematic view of a liver incorporating a shunt produced by a further intrahepatic portal-systemic stent in accordance with a second embodiment of the present invention.

MODES FOR CARRYING OUT THE INVENTION

A method in accordance with the present invention provides for the installation of a rigid, Palmaz-type, stent positioned in a hepatic parenchymal tract previously defined in the liver by way of known methods for connecting the systemic and portal veins. Furthermore, a flexible Wallstent™-type stent is then positioned inside the rigid Palmaz-like stent with the flexible stent being longer than the rigid stent in order that the ends of the flexible stent extend into the systemic and

portal veins, whereas a central portion of the flexible stent opposite the rigid stent and the rigid stent itself are positioned in the hepatic parenchyma. The provision of the flexible stent ensures that the fistula so-created follows the curve of the parenchymal tract joining the systemic and portal veins. The rigid stent helps in the prevention of the crushing of the anasmosis and also helps in preventing the unit made of the flexible and rigid stents from migrating in the liver. Depending on the respective diameters of both stents, the flexible stent will be deployed at least partly against the inside of the rigid stent for preventing the migration of the flexible stent.

Similarly, it is also contemplated to first install the flexible stent and to then insert the retracted rigid stent inside the expanded flexible stent, whereby the rigid stent can be deployed within the flexible stent and possibly to a diameter larger than that of the flexible stent thereby "over-extending" the flexible stent substantially opposite the rigid stent and thus securing the flexible stent to the rigid stent and preventing migration of the flexible stent in the liver.

Also in accordance with the present invention, there is provided an intrahepatic portal-systemic shunting device D which is schematically illustrated in Fig. 1. The present shunting device D embodies both a flexible and a rigid stent as will be explained in details hereinbelow. As in the prior art, the rigid stent of the shunting device D is adapted to be deployed by internal pressure using a

balloon catheter, whereas the flexible stent is distended by withdrawal of a sheath.

Reference is now made to Figs. 3 to 5 for the steps which precede the installation of the rigid and flexible stents of the present invention using the shunting device D of Fig. 1. After performing a percutaneous transhepatic portal vein catheterization, a balloon catheter 10 is lowered as seen in Fig. 3 and positioned across the parenchymal tract joining in the liver L the hepatic and portal veins H and P, respectively, as seen in Fig. 4. The balloon catheter 10 is then inflated with contrast medium to a predetermined diameter, e.g. 10 mm, as seen in Fig. 5. The balloon catheter 10 is then removed from the parenchymal tract, and the shunting device D, which is in fact a delivery catheter on which are mounted a flexible and a rigid stent, is then passed in an introducer sheath (not shown) and guided along a guide wire 12 into the parenchymal tract before being deployed thereat for producing the anasmosis. It is noted that the guide wire 12 was left in the liver L when the balloon catheter was removed. Accordingly, the delivery catheter or shunting device D is inserted over the guide wire 12 and is led to the parenchymal tract thereby.

Now referring to Figs. 1 and 2, the shunting device D comprises a pair of coaxial tubes 14 which include inner and outer tubes 16 and 18, respectively. A stainless steel tube 20 is inserted in the proximal end of the outer tube 18 and abuts therein a proximal end of the inner tube 16. The proximal end of the outer tube 18 is secured to a valve body 22 with the stainless steel tube 20 extending through the valve body 22 right up to the

proximal end of the inner tube 16. A proximal end of the stainless tube 20 is provided with a hub 24, whereby the guide wire 12 can extend through the stainless steel tube 20 and within the inner tube 18 of the coaxial tubes 14. A stopcock 26 is joined to the valve body 22 by way of an extension delivery tube 28 in such a way that fluid delivered through the stopcock 26, in an open position thereof, will be delivered to the annular passage defined in the coaxial tubes 14 between the inner and outer tubes 16 and 18. The distal end of the stainless tube 20 is sealingly connected to the proximal end of the inner tube 16 in order to prevent fluid conveyed through the stopcock 26 from entering the inner tube 16. The distal end of the guide wire 12 defines an elbow 30 which can act as a stopper, as explained hereinbelow.

The distal end of the coaxial tubes 14 is enlarged as embodying the rigid and flexible stents as well as other features which will now be presented. The outer tube 18 at the distal end thereof forms a two-ply invaginated rolling membrane 32 which comprises cylindrical inner and outer sheaths 34 and 36, respectively. A proximal end of the inner sheath 34 is bonded at 38 to the outside of the inner tube 16, with the proximal end of the outer sheath 36 corresponding to a continuation of the outer tube 18 upstream of the rolling membrane 32. Accordingly, fluid delivered through the stopcock 26 will be delivered along the annular passage defined between the inner and outer tubes 16 and 18 and, at the beginning or proximal end of the rolling membrane 32, the fluid will flow into the annular passage defined between the inner and outer sheaths 34 and 36 of the rolling membrane 32.

A rigid Palmaz-type stent 40 is positioned, in its compressed state, between the inner tube 16 and the inner sheath 34 of the rolling membrane 32. Opposite the rigid stent 40, the inner tube 16 is of a more elastic material so that fluid under pressure delivered in a lumen 42 defined in the inner tube 16 (and through which the guide wire 12 extends) will cause the inner tube 16 to inflate within the rigid stent. This inflatable portion of the inner tube 16 is referenced by the numeral 44 in Fig. 2.

A flexible Wallstent™-type stent 46 which is longer than the rigid stent 40 is disposed over the flexible stent 46 and between the inner tube 16 and the inner sheath 34 of the rolling member 32. Proximal and distal marker bands 48 are provided around the inner tube 16 adjacent to the proximal and distal ends of the flexible stent 46.

The distal end of the inner tube 16 is joined to a distal tip 50 which is of T-shaped cross-section while defining a central aperture for receiving therethrough the guide wire 12. The rolling membrane 32 at the folded distal end thereof surrounds the smaller proximal section of the distal tip 50 while generally abutting the enlarged distal section thereof. A seal may be provided at the central aperture of the distal tip 50 and/or on the guide wire 12, at a location downstream of the distal tip 50, in order to prevent leakage of a fluid supplied in the inner tube 16 through the central aperture of the distal tip 50.

The flexible stent 46 can be deployed by removing its covering sheath, that is the rolling membrane 32.

To distend the rigid stent 40, a fluid under pressure is supplied in the inner tube 16, possibly by way of the proximal end of the stainless tube 20, that is at the hub 24 thereof, whereby the inflatable portion 44 of the inner tube 16 will inflate thereby causing the controlled deployment of the rigid stent 40. The inflatable portion 44 thus resembles an angioplasty balloon and a saline solution can be used therefor.

Accordingly, the shunting device D of Figs. 1 and 2 can be installed in the parenchymal tract defined in the liver L between the portal and hepatic veins P and H, respectively, in accordance with the following method and reference is further made to Figs. 6 to 8 on that matter.

Once the flexible and rigid stents 46 and 40,. in their compressed state, have been properly positioned in the parenchymal tract, the valve body 22 can be slidably displaced along the stainless steel tube 20 in direction of the hub 24 thereof while not displacing the stainless steel tube 20 and the hub 24 in order that the inner tube 16 remains set thereby preventing relative displacement of the flexible and rigid stents 46 and 40 with respect to the parenchymal tract. A proper position of the flexible and rigid stents 46 and 40 is obtained by monitoring the position of the radiopaque marker bands 38. Through the stopcock 26, the extension delivery tube 28, the valve body 22 and the space between the inner and outer tubes 16 and 18, the

rolling membrane 32 becomes hydraulically pressurized between the inner and outer sheaths 34 and 36 thereof, at which point the rolling membrane 32 can be retracted by displacing the valve body 22 towards the hub 24 in order to deploy the flexible stent 46. As the outer tube 18 is connected to the valve body 22, the outer tube 18 is retracted along the stainless steel tube 20 also in direction of the hub 24, whereby the outer tube 10 retracts the outer sheath 36 of the rolling membrane 32 thereby displacing the fold of the rolling membrane 32 from the distal tip 30 in direction of the outer tube 18. The progressive retraction of the rolling membrane 32 uncovers the flexible stent 46 (from its distal end towards its proximal end) and, once the inner and outer sheaths 34 and 36 of the rolling membrane 32 are not superposed and are both disposed around the inner tube 16 upstream of the bonded area 38 of the inner sheath 34 to the inner tube 16, the flexible stent 46 will become completely distended as it is self-expanding.

With reference to Fig. 6, the rolling membrane 32 is shown retracted from the flexible stent 46, whereby the flexible stent 46 is deployed. In Fig. 7, the rolling membrane 32 and the outer tube 18 have been retracted, whereby the rigid stent 40 can now be distended using hydraulic pressure supplied in the lumen 42 of the inner tube 16. As the balloon portion 44 of the inner tube 16 is more elastic than the remainder of the inner tube 16, pressure supplied in the lumen 42 will cause the balloon portion 44 to inflate with the rigid stent 40 being distended thereby up to a predetermined diameter. Fig. 7 can also be considered to show both the flexible and rigid stents 46 and 40 in their

respective deployed positions. The inner tube 16 and the distal tip 50 attached thereto are then retracted by sliding within the expanded flexible and rigid stents 46 and 40. The guide wire 12 is also removed and Fig. 8 shows the end prostheses in place. The rigid stent 40 is basically positioned in the hepatic parenchyma whereas both flexible end portions of the flexible stent 46, that is the portions thereof located outwards of the rigid stent 40, are basically located in the hepatic and portal veins H and P, respectively. This configuration follows generally the curve required when joining the hepatic and portal veins H and P.

As seen by arrows 52 in Fig. 8, blood flowing upwards in the portal vein P towards the liver L will at least partly engage in the anastomosis produced by the flexible and rigid stents 46 and 40 and flow directly into the portal vein P, thereby substantially bypassing the liver L.

By distending the rigid stent 40 to a diameter which is greater than that of the flexible stent 46 when the latter is deployed, the rigid stent 40 will exert outward radial pressure on a central portion of the flexible stent 46, thereby preventing the migration of the flexible stent 46 in the liver L.

Fig. 9 is similar to Fig. 8 but illustrates a variant of the shunting device D of Figs. 1 and 2 and, more particularly, the flexible stent 46 of Fig. 8 is replaced by a pair of shorter flexible stents 46' which partly overlap the ends of the rigid stent 40.

Similarly to Fig. 9, it is also contemplated to have a rigid stent which is overlapped at only one of its ends by a flexible stent, that is basically the configuration shown in Fig. 9 but with only one flexible stent 46'.

It is further contemplated to modify the device of Fig. 2 in order that the rigid stent 40 is disposed outwardly around the flexible stent 46 with the rolling membrane 32 being located around the rigid stent 40 and also around the flexible stent 46 at the proximal and distal portions thereof with respect to the rigid stent 40, whereby the flexible stent 46 directly surrounds on its complete length the inner tube 16 and the rigid stent 40 is sandwiched between the rolling membrane 32 and the flexible stent 46. In such a case, the rolling membrane 32 is again first retracted for allowing the aforementioned proximal and distal portions of the flexible stent 46 to expand with the central portion of the flexible stent 46 located opposite the rigid stent 40 being prevented from deployment by the still collapsed rigid stent 40. Then, the inflatable portion 44 of the inner tube 16 located opposite the rigid stent 40 is inflated to deploy the rigid stent 40 with the central portion of the flexible stent 46 following due to its inherent self-expanding characteristic the deployment of the rigid stent 40. Such a variant of the device of Fig. 2 would thus provide for a flexible stent located within a rigid stent as described previously although the deployment of such a prosthesis would now require only one step and not two successive and distinct operations wherein the rigid stent is first positioned in the parenchymal tract followed by the insertion of the retracted flexible stent within the

deployed rigid stent which is finally followed by the deployment of the flexible stent. In all cases, the metallic prosthesis can be covered with an anticoagulative coating to avoid thrombosis.

In general, the present shunting devices are intended for patients awaiting a hepatic graft. With the present shunting devices, there is a decrease in the risks of rupture of the esophageal varices, in the risk of medico-resistant ascites while also improving the quality of life of the patients awaiting a graft. Accordingly, the present shunting devices can prolong the lives of patients which can therefore remain eligible for receiving a hepatic graft while impeding the deterioration of the patients' health.

It is noted that an introducer sheath should always be used for implanting the prosthesis as it will protect the hepatic tract especially in case a partially deployed stent must be withdrawn. The introducer sheath must be at a certain distance from the proximal area to be stented for allowing the rolling membrane to be retracted towards the introducer sheath during deployment of the flexible stent without the rolling membrane becoming inserted in the introducer sheath and thus possibly preventing the deployment of the stent.

The radiopaque marker bands 48 identify the constrained length of the stent but, since the stent shortens upon deployment, the markers 48 can only be used as approximate markers of the final stent position. Accordingly, radioscopic visualization of the stent itself is necessary to ensure precise stent placement.

During deployment of the flexible stent 46, the shunting device D can be pulled back slightly if partially deployed too far distally in the parenchymal tract, but a flexible stent 46 that is deployed too proximal cannot be advanced.

As the flexible stent 46 is gradually deployed, the pressure in the rolling membrane 32 will tend to fall, whereby it is necessary to constantly monitor this pressure to ensure that a proper pressure, e.g. 3.0 atm, is maintained, as lost of pressure can hinder the deployment of the flexible stent 46.

To retract the rolling membrane 32, it is important that the valve body 22 is gently slid up the stainless steel tube 20 toward the hub 24 while not pushing on the delivery system as the stainless steel tube 20 must be immobilized securely in order to prevent misalignment of the shunting device D and possible vessel damage. If the flexible stent 46 is partially deployed too far distally from the lesion sight, the flexible stent 46 can be pulled back but it is required to first deflate the rolling membrane 32. At least half of the flexible stent 46 must still be constrained by the rolling membrane 32 in order that the shunting device D may be repositioned in the parenchymal tract. After repositioning, the rolling membrane 32 is repressurized.

When only a Wallstent™ flexible stent is used, the implanted flexible stent may be further expanded by using a balloon dilatation catheter. With the present shunting device D, the rigid stent 40 and its dedicated dilatation balloon 44 can be

used to further expand the flexible stent 46 at least at the portion thereof located opposite the rigid stent 40. An independent dilatation balloon could be used to over-expand the end portions of the flexible stent 46.

After implantation, routine post-procedure portography can be performed to demonstrate the location and patency of the shunting device D.

CLAIMS:

1. An expandable prosthesis for a body passageway comprising first and second substantially tubular members, one of said first and second tubular members being substantially rigid with another one of said first and second tubular members being substantially flexible, said first and second tubular members each having a first collapsed diameter and at least a second expanded diameter, said first and second tubular members being adapted to at least partly overlap one another when installed in the body passageway, whereby said rigid member provides rigidity to the prosthesis while assisting in maintaining in position said prosthesis in the passageway, whereas said flexible member assists said prosthesis in substantially following the orientation of the body passageway.

2. A prosthesis as defined in Claim 1, wherein said first and second tubular members are distinct and each define openworks, at least when expanded.

3. A prosthesis as defined in Claim 2, wherein said rigid member is adapted to be expanded by outwardly directed radial forces while said flexible member is provided with intrinsic self-expanding forces, and wherein said flexible member is longer than said rigid member, whereby when said prosthesis is installed end portions of said flexible member extend outwardly past ends of said rigid member.

4. A prosthesis as defined in Claim 3, wherein said rigid member is adapted to be disposed within said flexible member.

5. A prosthesis as defined in Claim 3, wherein said flexible member is adapted to be disposed within said rigid member.

6. A prosthesis as defined in Claim 4, wherein the expanded diameter of said flexible member is smaller than the expanded diameter of said rigid member, whereby the deployment of said rigid member to said expanded diameter thereof within said flexible member causes at least a central portion thereof located between said end portions thereof to overextend thereby substantially securing said rigid and flexible member one to the other when installed in the body passageway.

7. A prosthesis as defined in Claim 5, wherein said rigid member is expanded to an expanded diameter thereof smaller than the expanded diameter of said flexible member thereby restricting the expansion of said flexible member at least at a central portion thereof located between said end portions thereof, whereby end portions of said flexible member expand to a larger diameter than said central portion for substantially securing said rigid and flexible member one to the other when installed in the body passageway.

8. A prosthesis as defined in Claim 2, wherein said rigid member is adapted to be

expanded by outwardly directed radial forces while said flexible member is provided with intrinsic self-expanding forces, said flexible and rigid members being adapted to be disposed, when installed in the body passageway, in an end-to-end and slightly overlapping relationship.

9. A prosthesis as defined in Claim 8, wherein said flexible member comprises a pair of distinct and similar sections with said rigid member being adapted to be disposed between said pair of sections when said prosthesis is installed in the passageway.

10. A prosthesis as defined in Claim 9, wherein said rigid member is adapted to be disposed partly within said flexible member, and wherein the expanded diameter of said sections of said flexible member is smaller than the expanded diameter of said rigid member, whereby the deployment of said rigid member to said expanded diameter thereof while ends of said rigid member are positioned within said sections of said flexible member causes ends of said sections overlapping said rigid member ends to overextend thereby substantially securing said rigid and flexible member one to the other when installed in the body passageway.

11. A shunting device for a body comprising an expandable prosthesis comprising first and second substantially tubular members, one of said first and second tubular members being substantially rigid with another one of said

first and second tubular members being substantially flexible, said first and second tubular members each having a first collapsed diameter and at least a second expanded diameter, catheter means for detachably carrying said prosthesis and for positioning said prosthesis in the body, expansion means for causing said first and second members to extend to the respective expanded diameters thereof, said first and second tubular members being adapted to at least partly overlap one another when installed in the body passageway, whereby said rigid member provides rigidity to the prosthesis while assisting in maintaining in position said prosthesis in the passageway, whereas said flexible member assists said prosthesis in substantially following the orientation of the body passageway.

12. A device as defined in Claim 11, wherein said first and second tubular members are distinct and each define openworks, at least when expanded, and wherein said rigid member is adapted to be expanded by outwardly directed radial forces while said flexible member is provided with intrinsic self-expanding forces.

13. A device as defined in Claim 12, wherein said flexible member is longer than said rigid member, whereby when said prosthesis is installed end portions of said flexible member extend outwardly past ends of said rigid member.

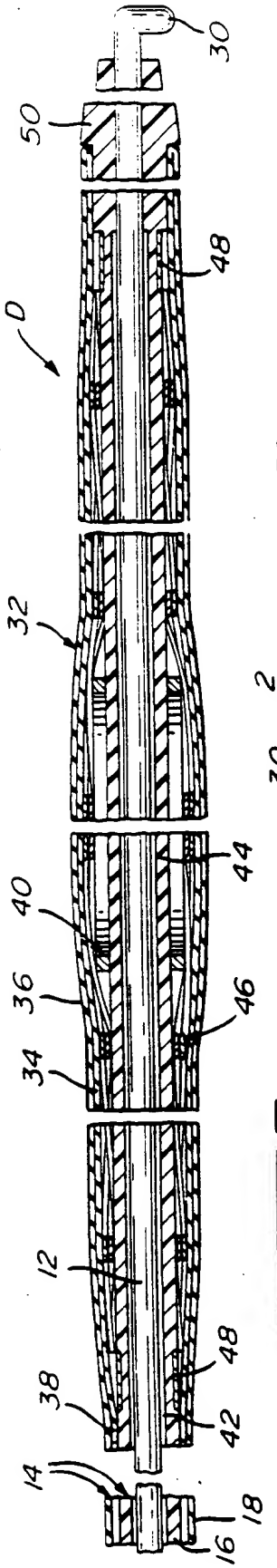
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FIG. 2

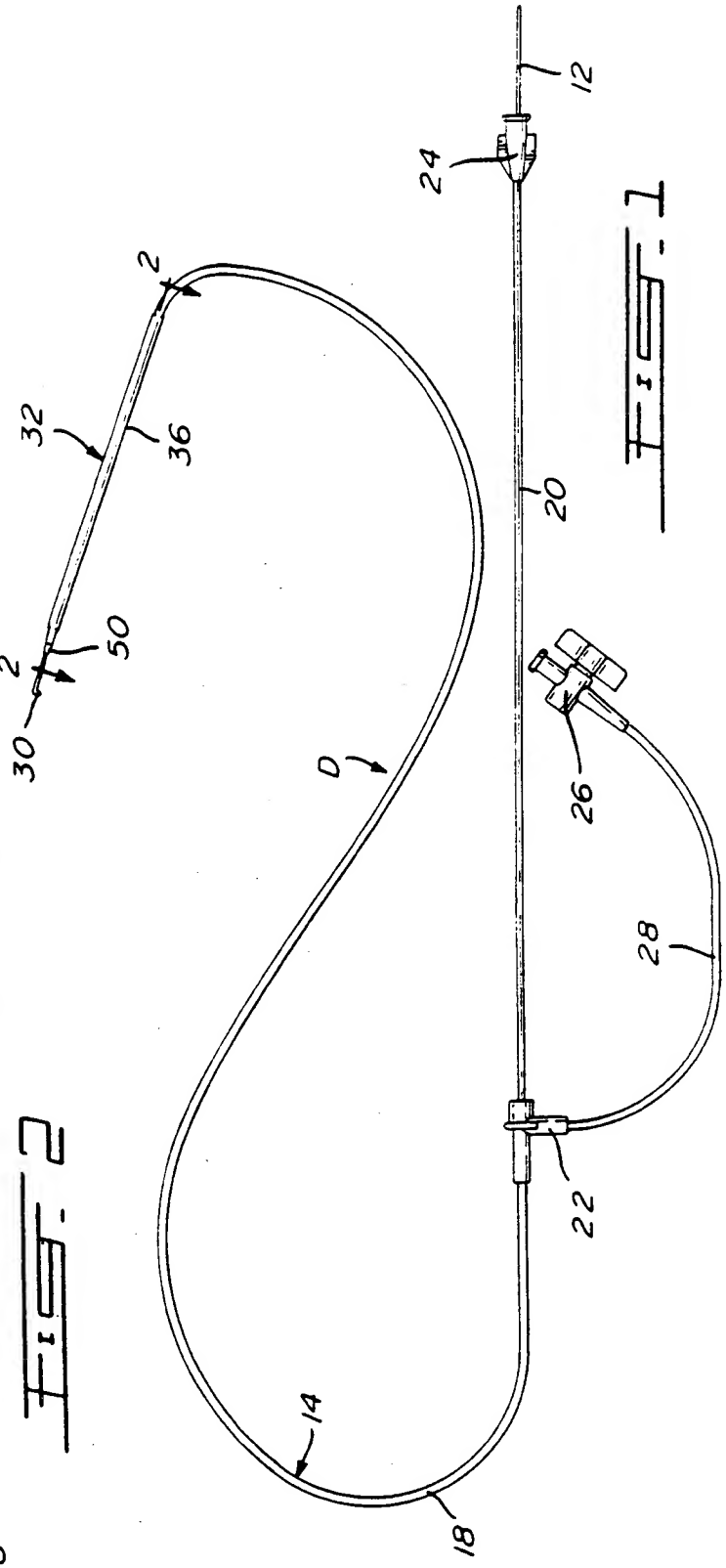
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FIG. 1

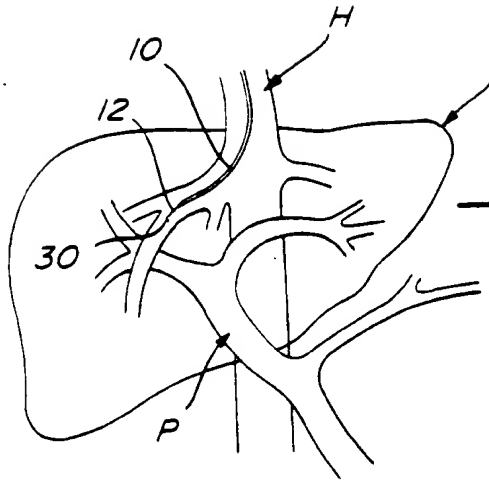

FIG. 3

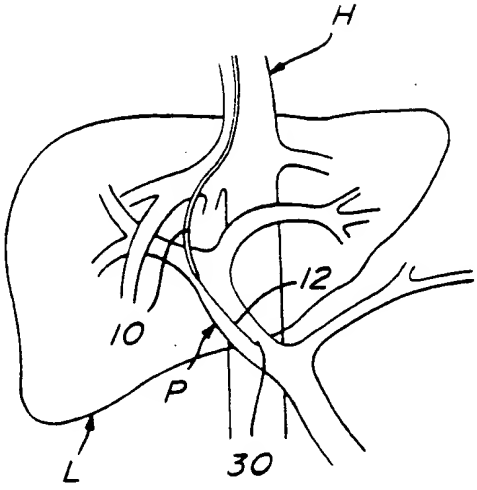

FIG. 4

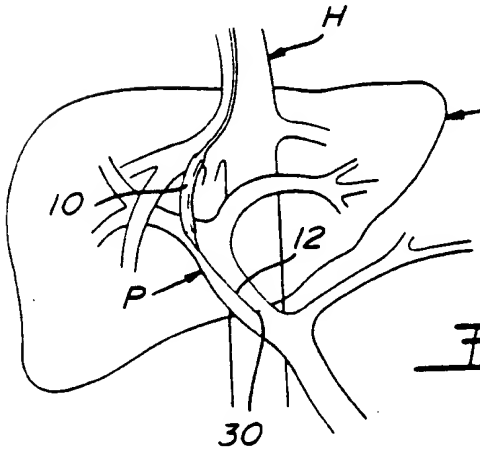

FIG. 5

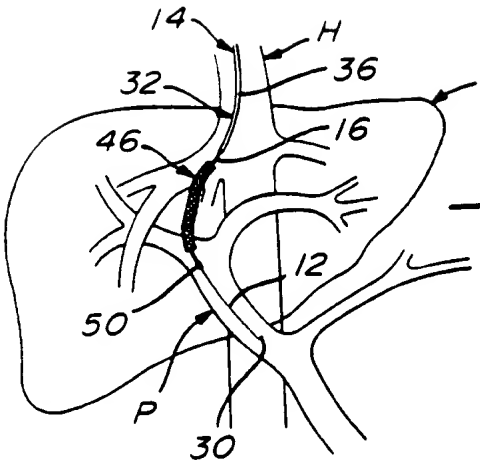

FIG. 6

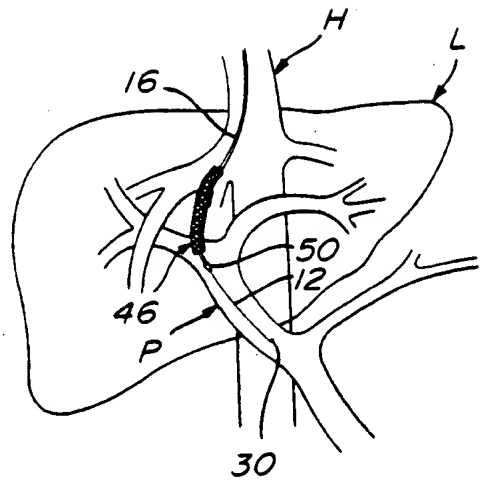

FIG. 7

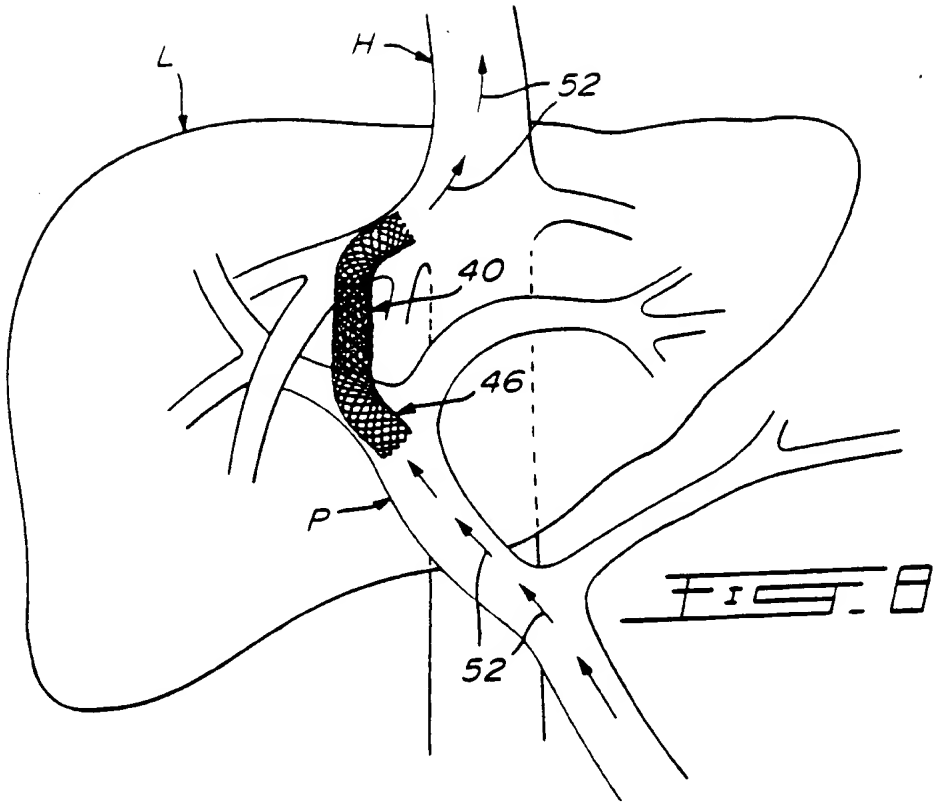

FIG. 8

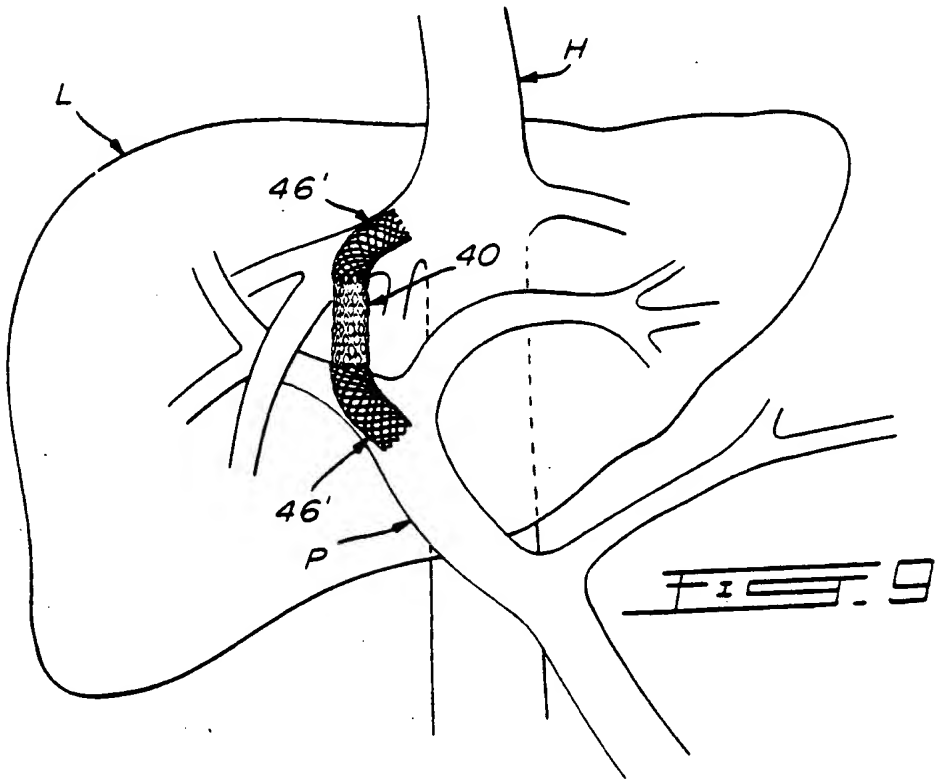

FIG. 9

INTERNATIONAL SEARCH REPORT

Internat Application No
PCT/CA 95/00124

A. CLASSIFICATION OF SUBJECT MATTER
IPC 6 A61F2/06

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC 6 A61F

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	EP,A,0 541 443 (MEADOX FRANCE) 12 May 1993 see the whole document	1-3,8,9, 11-13
Y	---	4-7
Y	US,A,5 064 435 (PORTER) 12 November 1991 see column 7, line 33 - line 46; figures	4-7
A	--- EP,A,0 421 729 (MEDTRONIC INC) 10 April 1991	1
A	--- EP,A,0 435 518 (MED INST INC) 3 July 1991	1
A	--- FR,A,2 525 896 (WALLSTEN) 4 November 1983	

☐ Further documents are listed in the continuation of box C.

☒ Patent family members are listed in annex.

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Date of the actual completion of the international search	Date of mailing of the international search report
13 June 1995	21.06.95

Name and mailing address of the ISA	Authorized officer
European Patent Office, P.B. 5818 Patentlaan 2 NL - 2280 HV Rijswijk Tel. (+ 31-70) 340-2040, Tx. 31 651 epo nl, Fax (+ 31-70) 340-3016	Sánchez y Sánchez, J

Form PCT/ISA/210 (second sheet) (July 1992)

INTERNATIONAL SEARCH REPORT

Information on patent family members

International Application No
PCT/CA 95/00124

Patent document cited in search report	Publication date	Patent family member(s)		Publication date
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		CA-A-	2082367	09-05-93
		US-A-	5383892	24-01-95
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		WO-A-	8303752	10-11-83
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		US-A-	4655771	07-04-87

PCT

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A1

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US
Filed on
08/206,511 (CON)
4 March 1994 (04.03.94)

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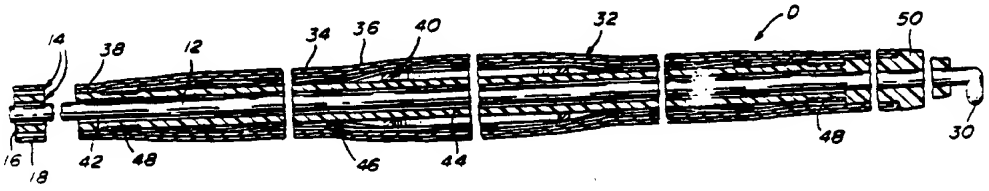
(81) Designated States: AM, AT, AU, BB, BG, BR, BY, CA, CH, CN, CZ, DE, DK, EE, ES, FI, GB, GE, HU, JP, KE, KG, KP, KR, KZ, LK, LR, LT, LU, LV, MD, MG, MN, MW, MX, NL, NO, NZ, PL, PT, RO, RU, SD, SE, SG, SI, SK, TJ, TT, UA, US, UZ, VN, European patent (AT, BE, CH, DE, DK, ES, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, ML, MR, NE, SN, TD, TG), ARIPO patent (KE, MW, SD, SZ, UG).

Published
With international search report.
With amended claims

Date of publication of the amended claims:
21 September 1995 (21.09.95).

(54) Title: ENDOVASCULAR HEPATIC PROSTHESES



(57) Abstract

An expandable prosthesis to be positioned in a parenchymal tract joining in the liver the hepatic and portal veins comprises a first substantially rigid tubular member and a second substantially flexible tubular member. The first and second tubular members each have a first collapsed diameter and at least a second expanded diameter and are adapted to at least partly overlap one another when installed in the body passageway. Basically, the rigid member provides rigidity to the prosthesis while assisting in maintaining in position the prosthesis in the passageway, whereas the flexible member assists the prosthesis in substantially following the orientation of the body passageway. In a shunting device, a catheter is provided for detachably carrying the prosthesis and for positioning the same in the body. An expandable balloon is used to expand the rigid tubular member, whereas the flexible tubular member which has intrinsic self-expanding forces expands when a sheath is removed. Therefore, the rigid and flexible tubular members are expanded to the respective expanded diameters thereof.

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VN	Viet Nam

AMENDED CLAIMS

[received by the International Bureau on 21 August 1995 (21.08.95);
original claims 1-7 amended; original claims 8-13 amended and renumbered as claims 10-15;
new claims 8, 9 and 16-20 added (7 pages)]

1. An expandable prosthesis for a body passageway comprising a substantially flexible and substantially tubular member and a substantially rigid and substantially tubular member, said flexible and rigid tubular members each having a pair of opposite outer ends and each further having a first collapsed diameter and at least a second expanded diameter, said flexible tubular member being axially longer than said rigid tubular member, said flexible and rigid tubular members being adapted such that, when installed in the body passageway, said rigid tubular member is disposed opposite said flexible tubular member and completely inwardly of said outer ends of said flexible tubular member, whereby said rigid tubular member provides rigidity to the prosthesis while assisting in maintaining in position said prosthesis in the passageway, whereas said flexible tubular member assists said prosthesis in substantially following the orientation of the body passageway.

2. A prosthesis as defined in Claim 1, wherein said flexible and rigid tubular members are distinct and each define an open weave, at least when expanded.

3. A prosthesis as defined in Claim 2, wherein said rigid tubular member is adapted to be expanded by outwardly directed radial forces while said flexible tubular member is provided with intrinsic self-expanding forces, and wherein said flexible tubular member comprises a central portion and a pair of end portions disposed axially on one side and another of said central portion, said central portion extending

opposite said rigid tubular member, whereby when said prosthesis is installed said end portions of said flexible tubular member extend outwardly past said outer ends of said rigid tubular member.

4. A prosthesis as defined in Claim 3, wherein said rigid tubular member is adapted to be disposed within said flexible tubular member.

5. A prosthesis as defined in Claim 3, wherein said flexible tubular member is adapted to be disposed within said rigid tubular member.

6. A prosthesis as defined in Claim 4, wherein the expanded diameter of said flexible tubular member is smaller than the expanded diameter of said rigid tubular member, whereby the deployment of said rigid tubular member to said expanded diameter thereof within said flexible tubular member causes at least said central portion to overextend thereby substantially securing said rigid and flexible tubular members one to the other when installed in the body passageway.

7. A prosthesis as defined in Claim 5, wherein said rigid tubular member is expanded to an expanded diameter thereof smaller than the expanded diameter of said flexible tubular member thereby restricting the expansion of said flexible tubular member at least at said central portion, whereby said end portions expand to a larger diameter than said central portion for substantially securing said rigid and flexible tubular members one to the other when installed in the body passageway.

8. An expandable prosthesis for a body passageway comprising a substantially flexible and substantially tubular member and a substantially rigid and substantially tubular member, said flexible and rigid tubular members each having a first collapsed diameter and at least a second expanded diameter, said flexible and rigid tubular members being adapted to be disposed in a longitudinally aligned and partly overlapping relationship when installed in the body passageway, wherein said flexible tubular member represents at least one of two longitudinal free ends of said prosthesis, whereby said rigid tubular member provides rigidity to the prosthesis while assisting in maintaining in position said prosthesis in the passageway, whereas said flexible tubular member assists said prosthesis in substantially following the orientation of the body passageway.

9. A prosthesis as defined in Claim 8, wherein said flexible and rigid tubular members are distinct and each define an open weave, at least when expanded.

10. A prosthesis as defined in Claim 9, wherein said rigid tubular member is adapted to be expanded by outwardly directed radial forces while said flexible tubular member is provided with intrinsic self-expanding forces, said flexible and rigid tubular members being adapted to be disposed, when installed in the body passageway, in an end-to-end and slightly overlapping relationship.

11. A prosthesis as defined in Claim 10, wherein said flexible tubular member comprises a pair of distinct and similar flexible sections with said rigid tubular member being adapted to be disposed between said flexible sections when said prosthesis is installed in the passageway , wherein said flexible sections and said rigid tubular member are disposed in an end-to-end and partly overlapping relationship with said flexible sections representing both said free ends of said prosthesis.

12. A prosthesis as defined in Claim 11, wherein said rigid tubular member is adapted to be disposed partly within said flexible tubular member, and wherein the expanded diameter of said flexible sections of said flexible tubular member is smaller than the expanded diameter of said rigid tubular member, whereby the deployment of said rigid tubular member to said expanded diameter thereof while ends of said rigid tubular member are positioned within said flexible sections causes ends of said flexible sections overlapping said rigid tubular member ends to overextend thereby substantially securing said rigid and flexible tubular members one to the other when installed in the body passageway.

13. A shunting device for a body comprising an expandable prosthesis and catheter means for positioning said prosthesis in the body, said prosthesis comprising first and second substantially tubular members, one of said first and second tubular members being substantially rigid with another one of said first and second tubular members being substantially flexible,

said first and second tubular members each having a first collapsed diameter and at least a second expanded diameter, said catheter means being adapted to detachably carry said prosthesis and to position said prosthesis in the body, expansion means for causing said first and second tubular members to extend to the respective expanded diameters thereof, said flexible tubular member being longer than said rigid tubular member, said rigid tubular member being adapted to at least partly overlap one another when installed in the body passageway, wherein said flexible tubular member represents at least one of two longitudinal ends of said prosthesis when installed in the body passageway, whereby said rigid member provides rigidity to the prosthesis while assisting in maintaining in position said prosthesis in the passageway, whereas said flexible member assists said prosthesis in substantially following the orientation of the body passageway.

14. A device as defined in Claim 13, wherein said flexible and rigid tubular members are distinct and each define an open weave, at least when expanded, and wherein said rigid tubular member is adapted to be expanded by outwardly directed radial forces while said flexible member is provided with intrinsic self-expanding forces.

15. A device as defined in Claim 14, wherein said flexible tubular member is longer than said rigid tubular member, said rigid tubular member being adapted to be disposed completely inwardly of opposite longitudinal ends of said flexible tubular member, whereby when said prosthesis is

installed end portions of said flexible tubular member extend outwardly past both longitudinal ends of said rigid member.

16. A device as defined in Claim 15, wherein said rigid tubular member is adapted to be disposed within said flexible tubular member, and wherein the expanded diameter of said flexible tubular member is smaller than the expanded diameter of said rigid tubular member, whereby the deployment of said rigid tubular member to said expanded diameter thereof within said flexible tubular member causes at least a central portion of said flexible tubular member located between said end portions to overextend thereby substantially securing said rigid and flexible tubular members one to the other when installed in the body passageway.

17. A device as defined in Claim 15, wherein said flexible tubular member is adapted to be disposed within said rigid tubular member, and wherein said rigid tubular member is expanded to an expanded diameter thereof smaller than the expanded diameter of said flexible tubular member thereby restricting the expansion of said flexible tubular member at least at a central portion of said flexible tubular member located between said end portions thereof, whereby said end portions of said flexible tubular member expand to a larger diameter than said central portion for substantially securing said rigid and flexible tubular members one to the other when installed in the body passageway.

18. A device as defined in Claim 14, wherein said flexible and rigid tubular members are

adapted to be disposed, when installed in the body passageway, in an end-to-end and slightly overlapping relationship.

19. A device as defined in Claim 18, wherein said flexible tubular member comprises a pair of distinct and similar flexible sections with said rigid tubular member being adapted to be disposed between said flexible sections when said prosthesis is installed in the passageway such that said flexible sections represent both said free ends of said prosthesis.

20. A device as defined in Claim 19, wherein said rigid tubular member is adapted to be disposed partly within said flexible tubular member, and wherein the expanded diameter of said flexible sections is smaller than the expanded diameter of said rigid tubular member, whereby the deployment of said rigid tubular member to said expanded diameter thereof while ends of said rigid member are positioned within said flexible sections causes ends of said flexible sections overlapping said rigid tubular member ends to overextend thereby substantially securing said rigid and flexible tubular members one to the other when installed in the body passageway.